UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,844	08/18/2003	Alfred J. Lewy	90,559-T	3196

7590 12/04/2007

McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
12/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,844	LEWY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-8,11-17 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-10,18-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are presented for examination.

Applicant's Amendment filed September 24, 2007 has been received and entered into the present application.

Claims 1-24 remain pending. Claims 9-10 and 18-19 remain under examination and claims 1-8, 11-17 and 20-24 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claim 9 is amended.

Applicant's arguments, filed September 24, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 and 18-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth at pages 4-8 of the previous Office Action dated March 22, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that Applicant is not claiming *per se* either genera of melatonin agonists or compounds that increase endogenous melatonin production. Applicant alleges that, "Different considerations apply when an applicant wishes to claim a broad class of compound as such, as opposed to a use of said compounds." (Applicant's remarks, p.6) Applicant submits that the extent of the required disclosure must take into account the knowledge regarding these

compounds that is already present in the art. Applicant asserts that the instant situation is distinct from the *Rochester* case because the art regarding melatonin *per se* and its agonists and compounds that could increase endogenous production of melatonin in a human was not in its infancy and relies upon publications (of which copies were not provided to the Office) to Krauchi et al. (*Sleep Research*, 24:526; 1995), Martinet et al. (*Pharmacology Biochemistry and Behavior*, 54:713-718; 1996), Redman et al. (*Psychopharmacology*, 118(4):385-390; 1995) and Sack et al. (*Biological Psychiatry*, 21:406-410; 1986) to support the allegation that the claimed melatonin agonists and compounds that increase endogenous melatonin production have adequate written description.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant alleges that the knowledge in the art with regard to the instantly claimed genus of melatonin agonists and compounds that increase endogenous melatonin production is sufficiently well developed such that the skilled artisan would have been able to immediately envisage those compounds capable of functioning in this manner and were, thus, amenable for use in the claimed method. In support of this position, Applicant relies upon four publications, three of which describe the same compound S-20098 as a melatonin agonist and one which describes the compound desmethylimipramine as a compound that increases endogenous melatonin production. However, while this supports the idea that the art at least recognized one compound of each of the claimed genera, it fails to establish that the skilled artisan would have easily, or at least with little expenditure of effort and/or experimentation, identified any other compounds that fall within the scope of the claimed genera and are capable of the claimed function. It is not enough to rely upon Counsel's own speculation that the claimed genera of agents is well characterized and well known in the art beyond these two compounds (i.e., S-20098 and desmethylimipramine) in the absence of any factual corroborating support demonstrating that at least a representative set of species of the genus are known in the art and, thus, are reasonably representative of

the full scope of compounds instantly claimed.

Though Applicant need not necessarily identify the exact chemical structure of each of the intended agents, in order to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, Applicant must provide *some* direction, either in the form of a common core structural element responsible for the function in acting as a melatonin agonist or a compound that increased endogenous melatonin production, or in the form of other physical and/or chemical properties, to provide some correlation between structure and function that may be used to aid in the identification of other compounds effective for performing these same functions. Please reference MPEP §2163, which states, "The written description requirement for a claimed genus [i.e., in the instant case, the claimed genus of melatonin agonists or compounds that increase endogenous melatonin production] may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus."

At best, Applicant has demonstrated two compounds, i.e., S-20098 and desmethylimipramine, were known in the art as, respectively, a melatonin agonist and a compound that increases endogenous melatonin production, in satisfaction of the written description requirement of 35 U.S.C. 112, first paragraph, but fails to present any description and/or disclosure of relevant identifying characteristics that would be supportive of establishing that Applicant was, in fact, in possession of the full scope of agents presently claimed. While this knowledge in the art of these two agents may provide adequate written description for *these two agents alone*, it fails to provide description of any other compound(s) that falls within the claimed genera such that these other members of the claimed genera could be immediately envisaged and/or readily identified. The idea that, in order to identify the other members of the genus,

one of skill in the art would have to undertake extensive hit or miss testing to determine the full scope of the genus is clearly indicative of the fact that Applicant was, in fact, not in possession of the entire scope of agents presently claimed. This is because Applicant cannot logically be in possession of that which he has yet to identify.

Regarding what is actually disclosed, the instant specification fails to provide any teaching, exemplary or otherwise, of compounds that are considered melatonin agonists and/or compounds that increase endogenous production of melatonin and would be amenable for use in the instantly claimed method. Though the art may very well recognize the compound S-20098 as a melatonin agonist and desmethylimipramine as a compound capable of increasing endogenous melatonin production, the fact that the specification places absolutely no limitation on the type, structure, properties, etc. of the claimed genera of melatonin agonists or compounds that increase endogenous melatonin production is indicative of the fact that the exemplification of one single agent of each of the two claimed genera clearly fails to be a number and/or selection of species that is representative of the entire breadth of agents encompassed by the claimed genera. In accordance with the written description requirement of 35 U.S.C. 112, first paragraph, substantial variation that exists within a large and highly varied genus of compounds requires *at least* a description of a representative number of species of the genus in order to satisfy the requirement.

It has long been held that, when there is substantial variation within a genus, one must describe a sufficient variety of species *to reflect the variation within the genus*. Given that Applicant has placed essentially no limitation on the identity of the compounds within the claimed genus of melatonin agonists and/or the claimed genus of compounds that are capable of increasing endogenous melatonin production, the identification of two species (one from each of the two claimed genera) fails to represent a variety of species that would reflect the substantial variation clearly present within the claimed genera such that it would have been clear that Applicant was, at least, in possession of the *full* scope of melatonin agonists

and/or compounds that increase endogenous melatonin production as instantly claimed.

Lastly, it is immaterial that the instantly claimed invention is directed to a method and not the claimed compounds *per se*. The fact that the instant claims are directed to methods and not compounds does not release Applicant from the need to provide adequate written description of the compounds for use in executing the claimed method. In fact, the compounds of the instant method are fundamentally essential to the practice of the invention as claimed such that adequate written description of said compounds must be provided in order to fully describe (and, thus, demonstrate that Applicant had possession of) the entire scope of the invention as instantly claimed.

For these reasons, and those previously made of record at pages 4-8 of the previous Office Action dated March 22, 2007, rejection of claims 9-10 and 18-19 remains proper and is **maintained**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 and 18-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lewy et al. (WO 95/05819; 1995), already of record, for the reasons of record set forth at pages 9-11 of the previous Office Action dated March 22, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that Lewy et al. restricted the amount of melatonin administered to an individual to prevent "spillover" of exogenously administered melatonin from one portion of the melatonin phase response curve (PRC) to the opposite portion. Applicant alleges that Lewy et al. teaches that such spillover can diminish the extent of the phase-shifting effect of exogenously-added melatonin by stimulating both portions of the PRC. Applicant submits that, in

contrast, the present invention uses higher doses of exogenous melatonin, administered in "more convenient, commercially-available dosage forms" (Applicant's remarks, p.9) and administered in a manner such that the overall level of melatonin is "greater in one portion of the melatonin PRC than the other (*i.e.*, CT6-CT18 *vs.* CT18-CT6)" (Applicant's remarks, p.9).

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

The basis of Applicant's traversal is unclear. Applicant fails to point directly to the portions of the Lewy et al. reference in which this alleged "spillover" effect is discussed. Furthermore, full consideration of the Lewy et al. failed to locate any portion of the reference that discusses this alleged "spillover" effect as asserted by Applicant. Accordingly, the teachings upon which Applicant relies to support this characterization of the cited reference are not clearly set forth for consideration by the Examiner. Applicant's discussion of the Lewy et al. reference, therefore, appears to amounts to no more than Counsel's own interpretation of the reference and is not grounded in the factual information that is actually disclosed by the reference.

Moreover, Applicant's traversal fails to raise any issues of material fact with regard to what Lewy et al. teaches and why these teachings do not directly anticipate the instantly claimed invention. Though Applicant asserts particular advantages of the instant invention, i.e., that it employs higher doses of exogenous melatonin administered in more convenient, commercially-available dosage forms, and that the overall level of melatonin is greater in one portion of the melatonin PRC than the other portion, Applicant is reminded that (1) the instant claims are not limited to a particular dosage amount and, thus, the assertion that the claims distinguish over Lewy et al. because the instant invention employs higher doses than those taught by the reference is clearly not persuasive because this feature upon which applicant relies is not recited in the rejected claims and (2) Lewy et al. explicitly teaches the administration of melatonin during the same period as that claimed (i.e., after CT18 and prior to about

CT1; claim 10) and, therefore, produces higher melatonin in this interval than from the corresponding portion of the PRC in which melatonin is not administered For these reasons, the teachings of Lewy et al. clearly anticipate the instant claims (and further in view of the fact that Applicant has failed to show otherwise).

Consequently, Applicant's arguments fail to clearly point out the patentable novelty which he thinks the claims present in view of the state of the art disclosed by the reference cited. In addition, the arguments also fail to specifically point out disagreements with the Examiner's contentions and/or how the claims avoid the reference or are distinguished from the same and are, therefore, clearly not persuasive in establishing that the evidence of novelty outweighs that proffered to support the instant conclusion of a lack of novelty.

For these reasons, and those previously made of record at pages 9-11 of the previous Office Action dated March 22, 2007, rejection of claims 9-10 and 18-19 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10 and 18-19 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44-48, 53-57 and 59 of U.S. Patent Application No. 10/945,843 and remain rejected under the judicially created doctrine of obviousness-type

double patenting over the method claims of U.S. Patent Nos. 5,242,941; 5,420,152; 5,591,768; 5,716,978; 6,638,963; and 6,794,407, each already of record, for the reasons of record set forth at pages 15-18 of the previous Office Action dated March 22, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejections, stating that the prior patents and/or prior patent applications require melatonin administration at reduced dosages so as not the result in elevated melatonin levels on both the advance and delay zones. Applicant states that the instant claims distinguish over the claims of the cited patents and/or patent applications because this dosage restriction is removed and allow for the administration of higher dosages provided that greater levels are produced in one zone than the other.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant alleges that the instant claims distinguish over those of the cited patent application and cited patents because the instant claims allow for the administration of higher dosages of melatonin than those of the copending and/or patented claims. However, it is noted that this feature upon which Applicant relies to demonstrate patentable distinction (i.e., that the melatonin dosage amounts are higher than those of the copending and/or patented claims) is not actually recited in the rejected claims. Please note that the instant claims do not recite a specific dosage amount, but rather are directed simply to "an amount of melatonin, melatonin agonist or compound that increased endogenous production of melatonin in the human" (see, e.g., instant claim 9) and are, therefore, not limited in such a manner to require, as Applicant alleges, a "higher" dose of melatonin than what is provided for in the copending and/or patented claims. Accordingly, Applicant is attempting to allege a patentable distinction of the instant claims over those of the copending application and the cited patents by asserting a feature that is clearly not claimed.

Moreover, the copending and/or patented claims clearly provide for the treatment of jet lag via achieving a circadian rhythm phase-delaying effect in a human by administering melatonin, a melatonin agonist or a compound that increases endogenous production of melatonin in the human at a time after CT18 and prior to CT1.

Furthermore, as previously noted in the Office Action of March 22, 2007, though the claims of U.S. Patent No. 6,638,963 (note that a representative rejection was set forth over the '963 patent and was clearly indicated to apply equally to the claims of each of the other cited application(s) and/or patents, but for the differences in claim numbering), recite the functional effect of administration of the melatonin, melatonin agonist or compound that increases endogenous melatonin production [i.e., the production of plasma melatonin or agonist concentration of greater than quiescent melatonin or equivalent agonist levels that overlaps offset of endogenous melatonin production, said greater than quiescent melatonin or equivalent agonist levels rise before the melatonin offset and fall after the melatonin offset (patented claim 1) or the production of a plasma melatonin or agonist concentration of greater than quiescent melatonin or equivalent agonist levels for a time or in a concentration that is different during a time interval from about CT6 to about CT18 than that produced during the time interval from about CT18 to about CT6 (patented claim 7)], which differs slightly from what is instantly claimed (i.e., the production in the human of a plasma melatonin or agonist concentration of greater melatonin or equivalent agonist levels during the time interval from about CT18 to about CT6 than from the time interval from about CT6 to about CT18), it is noted that the patented claims and the instant claims recite the administration of the same compound (i.e., melatonin, a melatonin agonist or a compound that increases endogenous melatonin production) to the same host (i.e., one suffering from jet lag and in need of a phase delay) at the same time (i.e., between CT18 and CT1), and, therefore, the functional effects of the patented claims are identical to the instant claims because products of identical composition cannot have mutually exclusive properties, particularly when administered under identical conditions and an identical host. Please see

MPEP §2112. For these reasons, the rejection of claims 9-10 and 18-19 under the judicially created doctrine of obviousness-type double patenting remains proper over the cited patent application and cited patents.

In the absence of persuasive argument by Applicant, and further in the absence of any Terminal Disclaimers in the record over the cited patent application and cited patents, the obviousness-type double patenting rejections of record remain proper for the reasons set forth at pages 15-18 of the previous Office Action dated March 22, 2007 and are, therefore, **maintained**.

Conclusion

Rejection of claims 9-10 and 18-19 remains proper and is **maintained**.

Claims 1-8, 11-17 and 20-24 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

November 29, 2007

12/2/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER